

## **REMARKS**

### **Claim Amendments**

Claims 1-7, 15-16, 18-22, 24-31, 34, and 35 are currently pending. Claims 8-14, 17, 23, 32, and 33 have been canceled without prejudice. Claims 1-7, 18, 20-22, 24, 25, and 35 are allowed. Claims 1, 4, 5, 15, 16, 24 and 25 have been amended with this response.

Claims 1, 4, and 5 have been amended merely to correct grammatical errors and matters of form. Claims 15, 16, 24, and 25 have been amended to recite that that transgenic tumor assay is a transgenic mouse tumor assay. Support for the amendment is found in the specification at page 34.

Amendments to the claims are made without prejudice and do not constitute amendments to overcome any prior art or other statutory rejections. Additionally, these amendments are not an admission regarding the patentability of subject matter of the canceled or amended claims and should not be so construed. Applicant reserves the right to pursue the subject matter of the previously filed claims in this or in any other appropriate patent application.

### **Allowed Claims**

Applicants gratefully acknowledge the allowance of Claims 1-7, 18, 20-22, 24, 25, and 35.

### **35 USC §112, First Paragraph Rejections**

#### **Written Description**

Claim 31 has been rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection of claim 31 for the reasons set forth below.

The Office argued that claim 31 has been amended to require the use of a tissue matched control, which embodiment is allegedly not supported by the originally filed disclosure which does not describe a tissue matched control sample contacted with a probe for MAP2K6 expression.

Contrary to the Office's allegation, the steps of claim 31 are thoroughly described, including the step of comparing the expression of MAP2K6 in a tumor sample with the expression of MAP2K6 in a tissue matched control sample. The method of claim 31 is described in the specification on pages 40-42. The specification teaches on page 40 that Taqman analysis is used to assess expression levels of the disclosed genes, including MAP2K6 gene, in various samples. On page 41, the specification teaches "[f]or each expression analysis tumor tissue samples are compared with matched normal tissues. A gene is considered overexpressed in a tumor when the level of expression of the gene is 2 fold or higher in the tumor compared with its matched normal sample." The results for the expression analysis in various tissues is shown in Table 1 (pages 41-42), which shows the number of pairs of tumor samples and matched normal tissue for the same patient and presents the results as the percentage of the samples with at least two-fold overexpression for each tumor type.

Similarly, the specification of the priority application 60/420554 describes the claimed method, including determining the expression of MAP2K6 in a tissue matched control sample, on pages 64 and 65. The specification teaches on page 64 that Taqman analysis is used to assess expression levels of the disclosed genes, including MAP2K6 gene, in various samples. Page 64 also describes obtaining normal and tumor tissues from the same patient. On page 65, the specification teaches "[f]or each expression analysis tumor tissue samples are compared with matched normal tissues. A gene is considered overexpressed in a tumor when the level of expression of the gene is 2 fold or higher in the tumor compared with its matched normal sample."

Applicants submit that the method of claim 31 is thoroughly described in the specification, including the embodiment of using a tissue matched control, such that one of skill in the art would recognize that Applicants had possession of the claimed invention. Applicants respectfully request withdrawal of the 35 USC 112, first paragraph, rejection of claim 31.

## **Enablement**

Claims 15 and 34 have been rejected under 35 USC §112, first paragraph, as allegedly failing to enable one skilled in the art how to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse the rejections of claim 15 and 34 for the reasons set forth below.

The Office alleged that the specification, while being enabling for a transgenic mouse expressing MAP2K6, does not reasonably provide enablement for a transgenic non-human animal expressing MAP2K6. Claims 15 and 16 have been amended to recite that the transgenic tumor assay is a transgenic mouse tumor assay, thereby obviating the rejection with respect to these claims. Applicants note that while claims 24 and 25 were indicated allowable, Applicants have also amended these claims to recite that the transgenic tumor assay is a transgenic mouse tumor assay.

Claims 34 and 35 recite the use of a non-human animal expressing MAP2K6. Applicants submit that the assays recited in claims 34 and 35, can include, but are not directed to the use of transgenic animals per se. The specification teaches on page 32 that the animal assays may rely on the endogenous expression of MAP2K6 and/or other genes, such as those involved in branching morphogenesis, or may involve engineered expression of genes. On pages 32-34, the specification provides several examples of appropriate animal models and assays that can be used in the present invention, including, for example, angiogenesis, tumorigenic, xenograft, hollow fiber, matrigel, and transgenic tumor assays. Only the transgenic tumor assays involve the use of a transgenic animal; the other assays do not involve the use of transgenic animals and should not be limited to mouse models. With respect to any recitation of an assay that involves the use of a transgenic animal, ie, in claims 15, 16, 24, and 25, the claims have been amended to recite that the transgenic animal is a mouse.

Applicants submit that the specification enables one skilled in the art to practice the methods claimed in 15-16, 24, 25, and 34-35. Accordingly, Applicants respectfully request withdrawal of the 35 USC 112, first paragraph rejections of claims 15, 16 and 34.

**Conclusion**

In view of the above remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions regarding this response, she is invited to call the undersigned attorney.

Date: August 3, 2010

Respectfully submitted,

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